

REMARKS

By this amendment, claims 22-25 are canceled without waiver or disclaimer of the subject matter contained therein. Claims 22-25 are canceled solely because of the finality of the restriction requirement with which Applicant continues to disagree with for the reasons of record.

Claims 1-21 remain pending in this application and have been rejected in the Office Action.

Rejection under 35 U.S.C. § 102

The Office has rejected claims 1-20 under 35 U.S.C. § 102(b) as being anticipated by Wilson et al. (U.S. Patent Application No. 2002/0099327) for the reasons noted on pages 2-4 of the Office Action. Applicant respectfully traverses this rejection.

To establish anticipation, the Office must show that “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.’ *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)... ‘The identical invention must be shown in as complete detail as is contained in the ... claim.’ *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).” *See M.P.E.P. § 2131.*

The Office argues that Wilson et al. describe a device that contains all of the features recited in the rejected claims. In particular, the Office argues that Wilson et al. describe a multi-lumen catheter that is “capable of being used as a tunneler.” Applicant submits that the Office has misinterpreted the disclosure of Wilson et al.

Each of the present claims includes a “tunneler” or similar claim language. As is seemingly understood by the Office, Wilson et al. do not actually disclose or describe a

“tunnel.” See, e.g., *Office Action at 2*. Thus, the Office’s argument that the device of Wilson et al. is “capable of being used as a tunnel” inherently recognizes that the limitation of “tunnel” is not present in Wilson et al. Accordingly, such an argument actually supports a conclusion that each and every element of the rejected claims is not described in Wilson et al.

Assuming, *arguendo*, the Office’s argument is applicable, Wilson et al. specifically disclose in several instances that the catheter 12 is pulled through a tunnel that has already been created in the desired location of the patient. Such disclosures teach away from the alleged “capable of being used” argument proposed by the Office.

First, the Abstract notes that a subcutaneous tunnel is created and the first end of the tunnel is near the incision, and “then” the catheter tube 12 is routed through the tunnel. Second, paragraph [0007] describes that a subcutaneous tunnel is created and then the catheter tube is routed from the first end through the second end of the tunnel. Third, paragraph [0038] describes that a tunnel of 8 cm to 10 cm should be created by means of “a tunnel” and then the catheter tube 12 is gently pulled through the tunnel. Finally, claim 1 of Wilson et al. notes that a subcutaneous tunnel is created and then the catheter tube is routed through the tunnel.

In light of all of these disclosures, Wilson et al. simply do not disclose a “tunnel” as claimed, and the skilled artisan would have come to the inescapable conclusion that a tunnel is created by a tunneler before the catheter tube 12 is inserted in the tunnel. Thus, the skilled artisan would have concluded that, contrary to the Office’s allegation, the catheter tube is not “used as a tunnel.” Simply put, since a tunnel already exists when the catheter 12 is used, the skilled artisan would have had no reason to use the catheter 12 as a tunnel.

Additionally, the Office also argues that Wilson et al. describe a gripping means (38, 40). Again, Applicant submits that the Office has misinterpreted the disclosure of Wilson et al.

Wilson et al. describe that the hub body 21 (which is connected to the catheter tube 12 after it is pulled through the tunnel) contains two suture wings 38 and 40 which are used to suture the catheter assembly 10 to the patient in the desired located after the catheter has been inserted. *See paragraphs [0022] and [0039]*. And the Office has not substantiated how the suture wings of a hub body—that are attached to the catheter after it has already been pulled through a tunnel—could be considered as a grip for the tip of a tunneler.

The Office also argues that Wilson et al. contain a protrusion 21(a) located on the outside of shaft members (14, 16) that retains the members in the lumen of the catheter 12. Yet again, Applicant submits that the Office has misinterpreted the disclosure of Wilson et al. Wilson et al. describe that the female threaded portion of the connector cover 34 receives the male threaded portion 21(a) of the hub body 21 to attach the hub assembly 20 to the catheter tube 12. *See paragraph [0040]*. In light of this disclosure, the skilled artisan would have understood that the male threaded portion 21(a) is used to connect the hub body 21 to the catheter. And the Office has not substantiated how such a disclosure would describe a protrusion on shaft members of a tunneler tip that retain those members in the lumen of a catheter.

The Office also argues that Wilson et al. discloses a shaft (12) that is removably connected to a tip (20). Such an argument ignores the fact that the rejected claims require a shaft of a tunneler, but that Wilson et al. expressly describe element 12 as a catheter. As well, it ignores the fact that Wilson et al. describe element 20 as a hub that is attached to the catheter 12 after it is pulled through a tunnel, not a tip of a tunneler that is used to create the tunnel.

Thus, the Office has not shown that Wilson et al. teach every limitation in the rejected claims. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

Rejection under 35 U.S.C. § 103

The Office has rejected claim 21 under 35 U.S.C. § 103 as being unpatentable over Imran (U.S. Patent No. 5964796) in view of Vardi et al. (WO 02/076333) for the reasons noted on pages 4-5. Applicant respectfully traverses this rejection for at least the reason that neither Imran nor Vardi et al., and certainly not their combination, teach or suggest each and every limitation of the claimed invention.

The Office alleges that Imran discloses “a gripping means 21.” *See Office Action at 4.* Applicants respectfully disagree. A review of Imran reveals that feature 21 is described by Imran as merely a body of an introducer sheath. *See column 3, lines 19-30.* Figure 2 illustrates feature 21, and based on that Figure, it is highly unlikely that the skilled artisan would consider feature 21 as a “gripping means.” And the Office has not argued, much less alleged, that Vardi et al. describe such a limitation. And since the Office has not substantiated that either reference teaches this feature, it is unlikely that the Office can show that their combination teaches such a feature.

Nor it is likely that the skilled artisan would have modified Imran as proposed by the Office. The Office proposes to modify the device of Imran to have introducer shaft members with different lengths. But Imran teaches that his introducer contain tubular members 31 that are sized to contain two catheters 13. *See column 4, lines 41-49.* These two catheters 13 are designed to have the same mechanical characteristics. *See column 5, lines 53-54.* Thus, the skilled artisan would have concluded that the tubular members 31 containing these similar catheters 13 should likewise have similar characteristics. And since the tubular members 31 should be similar, the skilled artisan would have had no reason to follow the Office’s proposed modification of making them with different lengths. Indeed, there would have been no

motivation to follow the proposed modification and make tubular members 31 with different lengths since that teaches away from the disclosure of Imran.

Thus, neither Imran nor Vardi et al., either alone or in combination, disclose or suggest each and every element of the claimed invention. Accordingly, Applicant respectfully requests withdrawal of this ground of rejection.

CONCLUSION

For the above reasons, as well as those of record, Applicant respectfully requests the Office to withdraw the pending grounds of rejection and allow the pending claims.

If there is any fee due in connection with the filing of this Amendment, including a fee for any extension of time not accounted for above, please charge the fee to our Deposit Account No. 50-0843.

Respectfully Submitted,

By


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Date: March 28, 2007